REMARKS

Claims 23-29[1] are active. Claims 23-29 and 30-32, which track the claims numbered as Claims 11-20 in the prior Amendment, are pending. For example, Claim 23 corresponds to Claim 11 (renumbered Claim 14). While Claims 30-32 are indicated as "New" to comply with Rule 126, they correspond to prior Claims 18-20 which were withdrawn from consideration.

Independent Claims 23 and 27 are directed to antibodies that have positive reactivity with cell lines U937 and K562. Support for this amendment is found in the specification on page 24, Table 1. Other minor editorial corrections have been made to the claims, for example, new Claims 28-29 (corresponding to Claims 16 and 17 in the prior Amendment) depend from Claim 27. Accordingly, the Applicants do not believe that any new matter has been added.

Election by Original Presentation

Claims 18-20 (corresponding to new Claims 30-32) were withdrawn from consideration as being directed to a non-elected invention. The Applicants traverse this requirement on the grounds that little additional burden would be imposed in the examination of these claims because they depend from Claim 23 which falls within the elected group of claims. However, in the event that the restriction requirement is maintained, the Applicants respectfully request that the claims of the nonelected groups which depend from or include all the limitations of those of Group I, be rejoined upon an indication of allowability for the elected claims, see MPEP 821.04.

[1] The Applicants thank Examiner Ouspenski for renumbering the non-entered claims and previously presented claims in accordance with the recent changes to Rule 126. For convenience, clarity and to assure the intended sequence of the claims is preserved, a new set of claims tracking the prior claims is presented.

Rejection—35 U.S.C. §112, first paragraph

Claims 14-19 (corresponding to new Claims 26-31) were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate description in the specification with respect to antibodies which bind to the genus of myeloid cells. This rejection is moot in view of the cancellation of Claims 14-19 and would not apply to new Claims 26-31 which are directed to an antibody which has a positive reactivity against cell lines U937 and K562.

U937 is a human monocytic cell line and K562 is a human cell line of chronic myeloblastic origin. A "monocyte" is a type of white blood cell which is distinct from lymphocytes (including B cells which produce antibodies) and granulocytes and its tissue counterpart is a macrophage. The term "myeloid" describes the non-lymphocyte groups of white blood cells. "Myeloblasts" are immature cells within the myeloid cell lineage.

Both of these cell lines and antibodies reacting with them are described in the specification, see e.g., Table 1 on page 24.

Rejection—35 U.S.C. §102

Claims 14-19 (corresponding to new Claims 26-31) were rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al., Jpn. J. Clin. Immun. 15(6):688 (1992) alone, and further in light of the evidence of the distribution of the RS38 antigen in Table 1 of the specification. The Applicants reiterate their prior arguments, but have further described the binding specificity of the claimed antibodies. The specific concerns raised in the Official Action are addressed below.

One concern was that if the prior art HN1.24 antibody and the antibodies of the present claims bind to the same polypeptide (SEQ ID NO: 1), then these antibodies are inherently the same. However, a long polypeptide, such as that of SEQ ID NO: 1, would

contain multiple structurally distinct epitopes[2] to which antibodies with different specificities would bind. In fact, the previously claimed antibodies have different specificities: they bind to myeloid cells, whereas the prior art HN1.24 antibody reacts "exclusively against B cells" (Goto, 1994, page 1924, col. 2, last paragraph) and "was unreactive with non-B-cell lines and carcinoma lines" (Goto, 1994, page 1926, col. 1, line 1).

However, an additional concern expressed at the bottom of page 6 of the Official Action, was that Goto (1994) is silent with respect to the reactivity of the prior art HN1.24 antibody with myeloid cells in general. However, it is stated that Goto (1994) does show the lack of reactivity of the HN1.24 antibody with particular myeloblastic and myelogenous leukemia cell lines. To further distinguish the binding specificity of the claimed antibodies, the present claims have now been directed to antibodies which react with U937 (a U937 human monocytic cell line) and K562 (a human cell line of chronic myeloblastic origin). The Applicants respectfully submit that Goto does not disclose with sufficient specificity nor suggest that the HN1.24 antibody would bind to these cell lines, in fact, Goto teaches away from such a binding specificity by indicating that the determinant bound by HN1.24 is specific to B cells.

Lastly, there was an inference by the Office that if the same antigen is expressed on different cell lines (e.g., on the B cells of Goto and on the myeloid cells shown in Table 1 of the specification), then the prior art antibody would inherently also bind to the myeloid cell lines in Table 1 via that antigen. Initially, the Applicants note that this inference is inconsistent with the experimental data of Goto (1994) which indicate that the prior art antibody is specific for B cells. B-cells are lymphocytes that produce antibodies. As discussed above, lymphocytes are a distinct type of white blood cells which differ from monocytes or myeloblastic cell lines, such as U937 and K562.

[2]Protein epitopes recognized by antibodies may contain about 6-10 sequential amino acid residues, but may also be conformation and comprise discontinuous determinants of a protein.

Nevertheless, even if two cell lines do express the same protein, they do not necessarily similarly present that protein as an antigen, or necessarily present the same epitopes of the protein. For example, the same polypeptide when expressed in different types of cells (such as in lymphocytes or in myeloblastic or monocytic cells) may be differentially expressed, transported, processed, folded, modified or masked.

When a reference is silent about an asserted inherent characteristic (i.e., that the prior art antibody would inherently bind to cells other than B-cells), the burden is on the Office to show that the missing characteristic is necessarily present in the prior art, Continental Can Co., USA v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); see also MPEP 2131.01(III)(page 2100-74, Rev. 2, May, 2004). In the present situation, this would be a difficult burden to meet since the prior art itself says that the prior art antibody is B-cell specific. Moreover, for the reasons discussed above with respect to differential antigen or epitope presentation, it would be difficult to show that the missing characteristic (binding to cells outside of the B lymphocyte lineage) is "necessarily present" in the prior art antibody.

Therefore, based on the experimental data in Goto (1994) which shows that the prior art antibody HN1.24 is specific for B-cells (a type of lymphocyte), the requirement in the present claims that the claimed antibodies bind to monocytic or myeloblastic (i.e., non-lymphocytic) cell lines U937 and K562, and in view of the capacity of different types of cells to present the same protein in different ways (or even not to present it as an antigen at all), the Applicants respectfully submit that this rejection would not apply to the pending claims.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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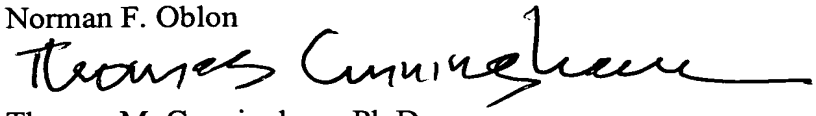

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